Ex. 1
To Plaintiffs' Brief On Foreign Regulatory Materials

MHRA
Regulating Medicines and Medical Devices

Guidance for manufacturers on reporting device-specific adverse incidents under the European vigilance system

To be read in conjunction with the European Commission's guidelines on a medical devices vigilance system MEDDEV 2.12/1

IVC filters

Report as individual events (in line with MEDDEV timescales)

- Death that is probably or possibly device-related
- Complications during deployment or placement eg:
  - premature release
  - partial or incomplete expansion
  - deformation (such as crossed or twisted legs or arms
  - asymmetric deployment (malapposition)
- Partial or multiple fractures
- Device migration/secondary movement with or without embolization
- Recurrent or fatal pulmonary embolism

Can be included in periodic summary reports (PSR)*

	Periodicity
IVC wall perforation / erosion / penetration >3mm	3 monthly
Retrieval difficulties / failure to retrieve	3 monthly
Progressive tilting / angulation	6 monthly

Report at the time the adverse trend is identified

- IVC wall penetration <3mm
- Vascular access and device placement related problems eg:
  - device misplacement / improper placement
  - pneumothorax
  - air embolism
  - haematoma / bleeding / haemorrhage
  - intimal tear
- Inferior vena cava thrombosis / occlusion / restriction of blood flow through the filter or venous insufficiency
- Systemic infection
- Adverse reaction

Generally not reportable

- Death if there is evidence that it is **not** device-related
- Access site thrombosis or stenosis
- Infection at puncture site

* If you can't use PSR, then report these events individually.

Ex. 2
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BARD DENALI IVC FILTER, FEMORAL (2016-02-16)

Report a Concern

Starting date:	February 16, 2016
Posting date:	February 22, 2016
Type of communication:	Medical Device Recall
Subcategory:	Medical Device
Hazard classification:	Type III
Source of recall:	Health Canada
Issue:	Medical Devices
Audience:	General Public, Healthcare Professionals, Hospitals
Identification number:	RA-57212

- Reason
- Affected products

Affected Products

BARD DENALI IVC FILTER, FEMORAL

Reason

Bard Peripheral Vascular is initiating a recall of specific product code/lot number combinations of Denali IVC filters following notice from the supplier of the stopcock assembly that these lots are at risk of having cracks in the stopcock body. This issue is isolated to the stopcock itself which is a component of the delivery system and remains external to the body throughout the surgical procedure.

Affected products

BARD DENALI IVC FILTER, FEMORAL

Lot or serial number

GFZJ0277
GFZJ0425

Model or catalog number

DL900F

Companies

Manufacturer	Bard Peripheral Vascular Inc. 1625 West 3rd Street Tempe 55441 UNITED STATES

Date modified: 2016-02-22

Ex. 3
To Plaintiffs' Brief On Foreign Regulatory Materials

(Filed Under Seal)

Ex. 4
To Plaintiffs' Brief On Foreign Regulatory Materials

(Filed Under Seal)

Ex. 5
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